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| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | EXAMINER HORNBERGER, JENNIFER LEA | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/579,014

Applicant(s)

KUHNS ET AL.

Examiner

JENNIFER L. HORNBERGER

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/14/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 25-27, 42-44, and 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 25, 42, and 52, it is unclear whether the holding body of the inner tube or the holding body of the outer tube is made in the form of a handle. Regarding claims 26, 43, and 53, it is unclear which holding body comprises the setting ring. Regarding claims 27, 44, and 54, it is unclear which holding body comprises at least one rib.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4, 9-12, 32, 35-38 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Pena (US 5,178,133).

Regarding claim 1, 9-11, and 35-37, Pena discloses a diagnostic device for pathologies of naturally occurring tubular anatomical structures comprising: a tubular elongated structure developing between a proximal end and a distal end and being adapted to be inserted in the tubular anatomical structure, means (12) for locally dilating the walls of the tubular anatomical structure being associated with the distal end of said elongated structure, said means for locally dilating being movable between a closed position for the introduction of the device and at least one open position (Fig. 3) for the viewing and evaluation of the pathology, said means further comprising a continuous membrane (34) for engaging dilating tissue in a continuous manner, wherein said membrane is elastic and transparent and externally covers the means for locally dilating, control means (14) being associated to the proximal end of the elongated structure (Fig. 1), said control means being operatively connected to said means for locally dilating in order to move them between the closed position and the open position (col. 4, ln. 13-22), and vice versa, said means for locally dilating having a rounded non-traumatic tip.

Regarding claims 4 and 32, Pena discloses said means for locally dilating comprise petals or arms (12) being arranged such that one first end thereof is associated to the distal end of the elongated tubular structure, said petals being adapted to assume at least one closed configuration and one open configuration (Fig. 2).

Regarding claims 12, 38, and 49, Pena discloses said elongated structure comprises an inner tube (13) and an outer tube (11) adapted to internally receive said inner tube, said inner tube and said outer tube being suitable to translate relatively to each other to open or close said petals (col. 4, ln. 13-22).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3734

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 4, 9-12, 24-29, 32, 35-38, 41-46, 49, and 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nady-Mohamed (US 5,353,784) in view of Pena (US 5,178,133).

Regarding claim 1, 9-11, and 35-37, Nady-Mohamed discloses a diagnostic device for pathologies of naturally occurring tubular anatomical structures comprising: a tubular elongated structure (10) developing between a proximal end and a distal end and being adapted to be inserted in the tubular anatomical structure, means (13,14) for locally dilating the walls of the tubular anatomical structure being associated with the distal end of said elongated structure, said means for locally dilating being movable between a closed position (Fig. 1) for the introduction of the device and at least one open position (Fig. 2) for the viewing and evaluation of the pathology, a control means (40) being associated to the proximal end of the elongated structure (Fig. 4), said control means being operatively connected to said means for locally dilating in order to move them between the closed position and the open position (col. 4, ln. 53-66), and vice versa, said means for locally dilating having a rounded non-traumatic tip. Nady-Mohamed disclose the means for locally dilating comprises a membrane for engaging dilating tissue in a continuous manner, but fails to disclose the membrane is continuous. Pena discloses a means for locally dilating (12) comprising a continuous transparent elastic membrane (34) externally covering dilating arms (12) for allowing the surgeon optimal viewing of the surgical field (see abstract). It would have been obvious to one of ordinary skill in the art to modify Nady-Mohamed to substitute the non-continuous membrane with a continuous transparent elastic membrane externally covering the means for locally dilating to achieve the same predictable result as evenly dilating the surrounding tissue in the surgical field. Substitution of one known

element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention.

Regarding claims 4 and 32, Nady-Mohamed discloses said means for locally dilating comprise petals or arms (13,14) being arranged such that one first end thereof is associated to the distal end of the elongated tubular structure, said petals being adapted to assume at least one closed configuration (Fig. 1) and one open configuration (Fig. 2).

Regarding claims 12, 38, and 49, Nady-Mohamed discloses said elongated structure comprises an inner tube (11) and an outer tube (10) adapted to internally receive said inner tube, said inner tube and said outer tube being suitable to translate relatively to each other to open or close said petals (col. 4, ln. 53-56).

Regarding claims 24, 41, and 51, Nady-Mohamed discloses said inner tube (11) comprises a holding body (18) arranged at a proximal end of the inner tube and wherein said outer tube (10) comprises a further holding body being arranged at a proximal end of the outer tube (Fig. 4).

Regarding claims 25, 42, and 52, Nady-Mohamed discloses said holding body is made in the shape of a handle (Fig. 4 and 7).

Regarding claims 26, 43, and 53, Nady-Mohamed discloses said holding body comprises a setting ring (61, 62) to define the position of the holding body corresponding to an open configuration of the device (Fig. 7).

Regarding claims 27, 44, and 54, Nady-Mohamed discloses the holding body further comprises at least one rib (62) to define at least one position of the holding body corresponding to an intermediate open configuration of the device (Fig. 7; col. 27-43).

Regarding claims 28, 45, and 55, said outer tube (10) comprise a holding body (40) being arranged at a proximal portion of the tube, said holding body (41) comprising a first

portion and a second portion (42), suitable to rotate relative to the first portion, and wherein there are further comprised means for turning the rotational movement of the first portion to a translational movement of the inner tube (11; col. 4, ln. 62 – col. 5, ln.11).

Regarding claims 29, 46, and 56, said outer tube (10) comprises a holding body (41) being provided with a trigger (42) adapted to rotate relative to the holding body and wherein there are provided means for turning the rotational movement of the trigger in a translational movement of the inner tube (11; col. 4, ln. 62 – col. 5, ln.11).

8. Claim 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nady-Mohamed (US 5,353,784) in view of Pena (US 5,178,133) as applied to claim 1 above, and further in view of Wallace (US 2,621,651). Nady-Mohamed fail to disclose a means of viewing adapted to be associated with the elongated tubular structure and to reach the tract of the tubular anatomical structure. Wallace et al. disclose a dilating instrument locally dilating tubular anatomical structures, the dilator comprising an elongated means of viewing (40) associated with a hollow elongated tubular member for viewing the dilated area. It would have been obvious to one of ordinary skill in the art to modify the dilation tool of Nady-Mohamed in comprise a means of viewing associated with the hollow elongated tubular member as suggested by Wallace et al. to allow the surgeon to view the surgical site.

9. Claim 8, 13, 34, 39, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nady-Mohamed (US 5,353,784) in view of Pena (US 5,178,133) as applied to claims 4, 12, 32, 38, or 49 above, and further in view of Bertolero et al. (US 2005/0159645).

Nady-Mohamed fails to disclose a petal and outer surface of the outer tube comprise at least one detection element or marker. However, Bertolero et al. disclose a detection element or marker on an outer sheath (paragraph 8) for determining the location in the body. It would have

been obvious to provide a detection elements or radiopaque marker on the outer tube and/or on at least one petal to allow the location of the device in the body to be determined.

10. Claims 30, 47, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nady-Mohamed (US 5,353,784) in view of Pena (US 5,178,133) as applied to claims 29, 46, and 56 above, and further in view of Williamson, IV et al. (US 5,972,004). Nady-Mohamed fails to disclose said trigger (212) comprises a toothed area (216) suitable to couple with a proximal grooved length (204), or a threaded length of the inner tube (202). Williamson et al. disclose a trigger (212) comprises a toothed area (216) suitable to couple with a proximal grooved length (218) of the inner tube for advancing a cutter distally (col. 16, ln. 27-30). It would have been obvious to substitute the coupling between the trigger to the inner tube in the device of Nady-Mohamed with the gear on the trigger and a rack on inner tube to achieve the same predictable result of trigger member causing the inner tube to move distally. Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention.

11. Claims 31, 48, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nady-Mohamed (US 5,353,784) in view of Pena (US 5,178,133) as applied to claims 29, 46, and 56 above, and further in view of Lapkin et al. (US 3,667, 474). Nady-Mohamed fails to disclose an elastic means being interposed between the holding body and the trigger to withdraw the latter in the resting position. Lapkin et al. disclose elastic means (30) interposed between a holding body (25) and a trigger member (26) for returning the inner member and holding members to their initial positions. It would have been obvious to one of ordinary skill in the art to provide Nady-Mohamed with an elastic member interposed between the holding member and the trigger member to provide an elastic force to return the members to their initial position as disclosed by Lapkin et al.

12. Claims 1, 4-12, 20-23, 32, 33, 35-38, 40, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788) in view of Pena (US 5,178,133).

Regarding claim 1, 9-11, and 35-37, Ewerhardt et al. disclose a diagnostic device for pathologies of naturally occurring tubular anatomical structures comprising: a tubular elongated structure (10) developing between a proximal end and a distal end and being adapted to be inserted in the tubular anatomical structure, means for locally dilating (12) the walls of the tubular anatomical structure being associated with the distal end of said elongated structure, said means for locally dilating being movable between a closed position (Fig. 1) for the introduction of the device and at least one open position (Fig. 2) for the viewing and evaluation of the pathology, control means (21) being associated to the proximal end of the elongated structure, said control means being operatively connected to said means for locally dilating in order to move them between the closed position and the open position, and vice versa (col. 3, ln. 47-51), said means for locally dilating having a rounded non-traumatic tip. Ewerhardt et al. fail to disclose a continuous membrane. Pena discloses a means for locally dilating (12) comprising a continuous transparent elastic membrane (34) externally covering dilating arms (12) for allowing the surgeon optimal viewing of the surgical field (see abstract). It would have been obvious to one of ordinary skill in the art to modify Ewerhardt et al. to include a continuous transparent elastic membrane externally covering the means for locally dilating to evenly dilate the surrounding tissue in the surgical field as suggested by Pena.

Regarding claims 4 and 32, Ewerhardt et al. disclose the means for locally dilating comprise petals (12) being arranged such that one first end thereof is associated to the distal end of the elongated tubular structure, said petals being adapted to assume at least one closed configuration (Fig. 1) and one open configuration (Fig. 2).

Regarding claim 5, Ewerhardt et al. disclose a petal comprises an arm which broadens into a curved surface (Fig. 2).

Regarding claim 6, Ewerhardt et al. disclose said curved surface has an asymmetric conformation with respect to the respective arm (Fig. 1).

Regarding claim 7, Ewerhardt et al. disclose said curved surface comprises a side extension suitable to overlap to the adjacent petal at least in the closed configuration of the petals (Fig. 1).

Regarding claims 12, 38, and 49, Ewerhardt et al. disclose said elongated structure comprises an inner tube (21) and an outer tube (10) adapted to internally receive said inner tube, said inner tube and said outer tube being suitable to translate relatively to each other to open or close said petals (col. 3, ln.15-19).

Regarding claim 20, Ewerhardt et al. disclose said petals (12) are formed as one piece with said outer tube (10; Fig. 1).

Regarding claim 21, Ewerhardt et al. disclose each petal (12) couples with a portion of said inner tube (21) forming a unidirectional guide adapted to close or open the petals subsequent to the translation of the inner tube relative to the outer tube and the petals (Fig. 2).

Regarding claim 22, Ewerhardt et al. disclose each petal (12) comprises a longitudinally extending rib (17) and wherein said inner tube (21) comprises a distal flange (15) provided with openings (16) adapted to couple with respective ribs (17) of said petals (col. 2, ln. 105-120).

Regarding claim 23, Ewerhardt et al. fail to disclose wherein said rib (17) has a T-shaped cross-section and wherein said openings has a C-shaped cross-section suitable to couple with the cross-section of a respective rib. It would have been an obvious matter of design choice to give the rib a T-shaped cross section and the openings of the inner tube of the distal flange a C-shaped cross section, since applicant has not disclosed that the particular coupling

solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the ribs and the openings having any shaped cross-sections which fit together.

Regarding claim 33, Ewerhardt et al. disclose at least one arm comprises a straight length suitable to be fixed to the elongated structure and a curved length (Fig. 2).

Regarding claim 40, Ewerhardt et al. disclose an outer surface of the outer tube (10) has grooves (11) adapted to receive at least one portion of an arm (12), respectively (Fig. 1).

13. Claims 1, 4, 9-12, 14-19, 32, 35-38, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sijp (DE 19828099 A1) in view of Pena (US 5,178,133).

Regarding claim 1, 9-12, and 35-37, Sijp discloses a diagnostic device for pathologies of naturally occurring tubular anatomical structures comprising: a tubular elongated structure (1) developing between a proximal end and a distal end and being adapted to be inserted in the tubular anatomical structure, means for locally dilating (3) the walls of the tubular anatomical structure being associated with the distal end of said elongated structure, said means for locally dilating being movable between a closed position (Fig. 1) for the introduction of the device and at least one open position (Fig. 2) for the viewing and evaluation of the pathology, control means (5,6) being associated to the proximal end of the elongated structure, said control means being operatively connected to said means for locally dilating in order to move them between the closed position and the open position, and vice versa (Fig. 4-5), said means for dilating having a rounded non-traumatic tip. Sijp fails to disclose a continuous membrane. Pena discloses a means for locally dilating (12) comprising a continuous transparent elastic membrane (34) covering dilating arms (12) for allowing the surgeon optimal viewing of the surgical field (see abstract). It would have been obvious to one of ordinary skill in the art to modify Ewerhardt et al. to include a continuous transparent elastic membrane externally

covering the means for locally dilating to evenly dilate the surrounding tissue in the surgical field as suggested by Pena.

Regarding claims 4 and 32, Sijp discloses the means for locally dilating comprise petals (3) being arranged such that one first end thereof is associated to the distal end of the elongated tubular structure, said petals being adapted to assume at least one closed configuration (Fig. 1) and one open configuration (Fig. 2).

Regarding claims 12, 38, and 49, Sijp discloses said elongated structure comprises an inner tube (10) and an outer tube (1) adapted to internally receive said inner tube, said inner tube and said outer tube being suitable to translate relatively to each other to open or close said petals (Fig. 4-5).

Regarding claim 14, Sijp discloses said inner tube (1) has an annular groove adapted to receive and draw an end of said petals (3; Fig. 3-5).

Regarding claim 15, Sijp discloses said outer tube (10) has openings to receive said petals (Fig. 3-5).

Regarding claim 16, Sijp discloses at an opening said outer tube (10) comprises a notch suitable to be inserted inside an aperture (4) of a respective petal (3).

Regarding claim 17, Sijp discloses said inner tube (1) has a distal grooved length or a threaded length adapted to receive and draw an end of a petal (3) comprising a toothed area (8; Fig. 3).

Regarding claim 18, Sijp discloses said outer tube (218) has openings to receive said petals (Fig. 4-5).

Regarding claim 19, Sijp discloses wherein at an aperture said outer tube (218) has seats (4) adapted to receive a pivot (8) of a corresponding petal (3; Fig. 3-5).

Response to Arguments

14. Applicant's arguments, see page 1, filed 04/14/2009, with respect to Kerr have been fully considered and are persuasive. The rejection over Kerr has been withdrawn. However, applicant failed to address how the claim amendments distinguish the instant invention from the previous 35 U.S.C 103(a) rejections based on primary references Nady-Mohamed, Ewerhardt et al. and Sijp. It is the examiner's position that each of these devices meets the newly amended claim language diagnostic devices for pathologies of naturally occurring tubular anatomical structures, wherein said means for locally dilating has a rounded non-traumatic tip. Therefore, the rejections based on Nady-Mohamed, Ewerhardt et al. and Sijp are maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
05/18/2009

/Todd E Manahan/
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